REMARKS

The present application is directed to a method of detecting anti-tumour autoantibodies in an individual by detecting complexes formed by the binding of autoantibodies in a sample from the individual with tumour marker proteins isolated from a bodily fluid obtained from a body cavity or space in which a tumour is or was present or associated with in a cancer patient.

To rectify the defective Declaration on file with the USPTO, applicants enclose herein a replacement Declaration.

Claims 1-8 and 11-18 are pending. Claims 13-14 are cancelled. Claims 15-18 are withdrawn as directed to non-elected species. Claims 9, 10 and 19-38 are cancelled as directed to non-elected subject matter. Claims 1-8, 11-12, and 15-18 are amended. Applicants respectfully submit that the amendments to the claims introduce no new matter.

Restriction Requirement and Election of Species

The Examiner maintained the Restriction Requirement and noted that Claims 15-18 do not read on the elected species of ras as the tumour marker protein.

Applicants have cancelled non-elected Claims 9, 10 and 19-38 and have withdrawn Claims 15-18. Cancellation of Claims 9, 10 and 19-38 should not be considered forfeiture of this subject matter, and applicants reserve the right to pursue the cancelled subject matter in one or more divisional applications.

Information Disclosure Statement

A copy of JP 09 189702 (Reference #10 on the previously submitted Information Disclosure Statement) is enclosed.

Oath/Declaration

A replacement Oath/Declaration is enclosed.

Objections to the Specification

Applicants have verified the non-initialed alterations in the title on page 1 of the file copy by accessing the application through the PAIR system and have amended the specification accordingly to reinsert the original title.

Applicants have amended the specification to include a cross-reference to related applications.

Applicants have amended the specification to indicate trademarks by use of capitalization and generic terminology. However, applicants have not located the specific trademark "PinPoint" in the specification, as mentioned by the Examiner,.

Claim Objections

The Examiner indicated that Claim 2 recited a duplication of the word "of". Applicants cannot locate this duplication in Claim 2. However, applicants respectfully submit that other amendments to this claim may have removed the duplication that the examiner observed.

The Examiner objected to Claims 11, 13 and 17 as depending from non-elected Claim 10. Claims 11and 17 have been amended accordingly, and Claim 13 has been cancelled.

Rejections under 35 USC § 112

Claims 1-8, 11-14, 17 and 18 were rejected under 35 USC § 112, second paragraph, as indefinite. The Examiner noted that the claims did not clarify any relationship between the kind or type of cancer that the auto-antibodies were directed against and the cancer patients from which the immunoassay reagents were obtained, certain terms and phrases were unclear, and improper Markush group language was used.

Applicants have amended the claims to clarify that the immunoassay reagents are obtained from a cancer patient and the auto-antibodies can be detected in a sample from an individual. The terms, phrases and Markush group language have been amended accordingly.

Support for the term "isolated" can be found on page 6, paragraph 4, of the specification.

Rejections under 35 USC § 102(b)

Claims 1-8, 11-14, 17 and 18 were rejected under 35 USC § 102(b) as anticipated by published PCT application WO 99/58978 to Robertson *et al.* (the "Robertson PCT"). Applicants respectfully traverse.

The Robertson PCT describes an assay for detecting cancer by using a cancer-associated MUC1 protein isolated from a patient blood sample. A normal MUC1 protein isolated from urine is used as a control. (See page 21, lines 28-34 of the Robertson PCT.) Applicants respectfully submit that the Robertson PCT fails to isolate tumour marker proteins from a bodily fluid obtained from a body cavity or space **where a tumour is or was present or associated** as claimed in the present application.

On page 45, line 7-15, the Robertson PCT describes the presence of pleural effusion as evidence that a malignancy existed in urologically "benign" subjects being examined. In other words, the pleural effusion represented clinical evidence of other malignancies. However, no fluid from the pleural effusion was used as a source of tumour marker proteins.

For at least the foregoing reasons, applicants respectfully submit that the claimed method is novel over the Robertson PCT and respectfully request that the rejections under 35 U.S.C. §102(b) be withdrawn.

Claims 1-8, 11-14, 17 and 18 have been rejected under 35 USC § 102(b) as being anticipated by Luo *et al.* (*British J. Can.* 87:339-343, 2002). Applicants respectfully traverse.

Luo *et al.* describe the serological screening of an ovarian carcinoma cDNA expression library with ascites fluid pooled from ovarian cancer patients. Several tumour antigens were identified, including heat shock protein 90 (hsp90), which was then used to determine the prevalence of hsp90 autoantibodies in patients using an immunoassay. The immunoassay reagents taught by Luo *et al.* are the hsp90 proteins encoded by the cDNA

library. Applicants respectfully submit that these immunoassay reagents were not isolated from a bodily fluid obtained from a body cavity or space in which a tumour is or was present or associated as claimed in the present application.

For at least the foregoing reason, applicants respectfully submit that the claimed method is novel over Luo *et al.* and respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

Claims 1-7 have been rejected under 35 USC § 102(b) as being anticipated by published PCT application WO 00/26668 to Hanash *et al.* (the "Hanash PCT"). Applicants respectfully traverse.

The Hanash PCT teaches diagnostic assays in which increased levels of S100 protein or the presence of S100 autoantibodies are detected in serum or other biological fluids of a subject. Contrary to the Examiner's assertion, page 6, line 3 of the Hanash PCT fails to teach that the S100 proteins are obtained from bodily fluids. This section of the Hanash PCT mentions that protein mixtures, such as sera and other biological fluids, may contain S100 proteins that can be prepared or assayed for increased levels of protein expression. In other words, the bodily fluids represent the **sample**, not the source of the reagent. On page 11, lines 23-31, the Hanash PCT teaches that S100 protein can be obtained using recombinant DNA techniques. Alternatively, the Hanash PCT teaches that S100 can be purified from natural sources, such as cells, using protein separation techniques well known in the art.

Applicants respectfully submit that the Hanash PCT fails to teach the isolation of tumour marker proteins from a bodily fluid at all and certainly fails to teach the isolation of tumour marker proteins from a biological fluid obtained from a body cavity or space in which a tumour is or was present or associated as claimed in the present application.

For at least the foregoing reason, applicants respectfully submit that the claimed method is novel over Hanash *et al.* and request that the rejection under 35 U.S.C. §102(b) be withdrawn.

Double Patenting Rejections

Claims 1-8, 11-14, 17 and 18 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4, 8 and 9 of copending Patent Application No. 10/417,633 (the "'633 application"; US 2003/0232399) in view of the Robertson PCT.

Applicants respectfully submit that Claims 1, 4, 8 and 9 of the '633 application have not yet been allowed. Therefore, applicants wish to defer the consideration of filing a Terminal Disclaimer in response to this rejection until allowable subject matter in the '633 application is established.

Claims 1-8 and 11-18 have been provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over Claims 1, 4, 8, 19, 20 and 24 of copending Patent Application No. 09/881,339 (the "'339 application"; US 20030138860) in view of the Robertson PCT.

Applicants respectfully submit that Claims 1, 4, 8, 19, 20 and 24 of the '339 application have not yet been allowed. Therefore, applicants wish to defer the consideration of filing a Terminal Disclaimer in response to this rejection until allowable subject matter in the '339 application is established.

CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed April 5, 2007. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned is respectfully solicited.

Respectfully submitted,

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